PhISTAR
Pharma Instinct Skill Training & Research

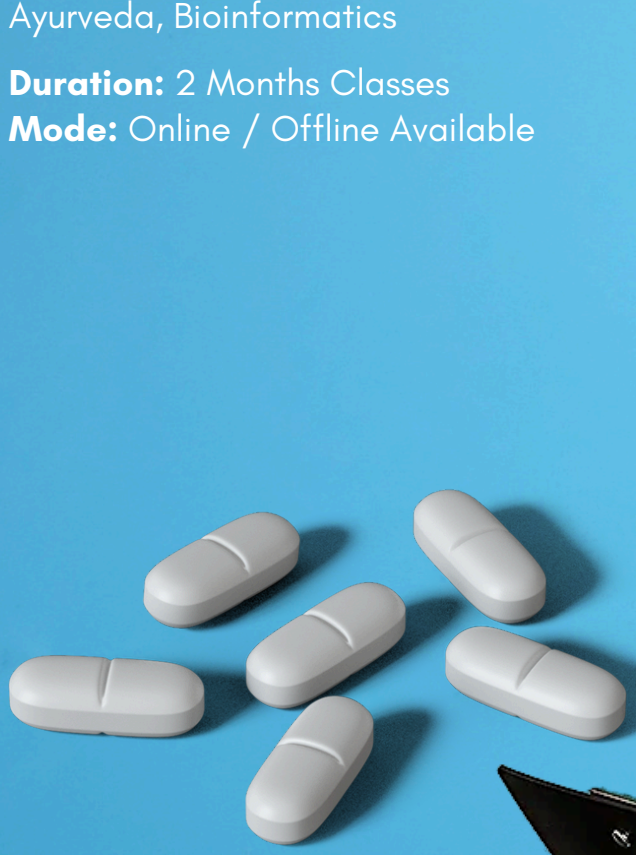
Pharma Instinct

INTENSIVE

CLINICAL TRIAL MONITORING COURSE

Eligibility: BDS, BAMS, M. Pharma, B.Pharma, M. Sc./ M.Tech/ B. Sc./ B.Tech. in Biotechnology, Microbiology, Biochemistry, Molecular Biology, Ayurveda, Bioinformatics

Duration: 2 Months Classes
Mode: Online / Offline Available



PROGRAMME MODULES:

MODULE 1: INTRODUCTION TO CLINICAL TRIALS

- Overview of clinical research and its importance in drug development.
- Phases of clinical trials (Phase I-IV) and their objectives.
- Role of Clinical Trial Monitoring in ensuring trial success.

MODULE 2: ROLES AND RESPONSIBILITIES OF A CLINICAL RESEARCH ASSOCIATE (CRA)

- Core duties of a CRA, including site visits, monitoring, and reporting.
- Understanding trial protocols, informed consent, and patient safety.
- Managing trial documentation, from investigator files to regulatory submissions.

MODULE 3: SITE MONITROING

- Building effective relationships with clinical trial sites.
- Clinical Trial Monitoring and its types.
- Techniques for monitoring and auditing site performance.
- Troubleshooting and resolving site issues to maintain compliance.

MODULE 4: DATA INTEGRITY AND TRIAL DOCUMENTATION

- Best practices for maintaining trial documentation and source data verification.
- Ensuring accurate and complete data collection at clinical sites.

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